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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
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PISCATAWAY, NJ 08855

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/439 889

Applicant(s)

SH: et al

Examiner

Naff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/4/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 6, 8 + 9 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 6, 8 + 9 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The amendment of 6/4/03 canceled claims 4, 5 and 7, amended claims 1, 2 and 6, and added new claims 8 and 9.

Claims examined on the merits are 1, 2, 6, 8 and 9 which are all claims in the application.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

10 Claims 1, 2, 6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In step d of claim 1, it is unclear as to whether the array is still frozen after the freezing in step c. Additionally, if still frozen during drying, it is unclear how drying of the frozen pads can occur without using reduced pressure during drying.

5 Claim 2 is unclear by not having antecedent basis in claim 1 for a freeze-dried array produced by the method of claim 1 since claim 1 does not require freeze drying. Merely freezing in step c of claim 1 does not require freeze drying since the array in step d is not required to be frozen and drying under reduced pressure.

10 Claim 2 is further unclear in line 2 as to what constitutes the specific substance required to be bound to the pads since claim 1 does recite "specific substance". Claim 1 requires adding an oligonucleotide probe to the pads, and not a "specific substance".

 Claims 8 and 9 are unclear by reciting "The array of claim 1"
15 since claim 1 is drawn to a method and not an array.

Claim Rejections - 35 USC § 103

 Claims 1, 2, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guschin et al or Khrapko et al (5,552,270) or Chetverin et al (5,616,478) in view of Funk et al (5,973,014), and if
20 necessary in further view of Ruchel (1978) or Ruchel (1975) or Blank et al for reasons set forth in the previous office action of 2/11/03 and for reasons herein.

 The claims are drawn to a method of producing an oligonucleotide array by providing an array of porous polymer gel pads on the surface
25 of a solid support, adding an oligonucleotide probe to each of the

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porous pads, freezing the array of porous pads containing the oligonucleotide probe, and drying the array of porous polymer pads for a time sufficient to obtain porous polymer pads having increased pore size. Also claimed is an oligonucleotide array of freeze-dried porous polymer gel pads on a solid support prepared by the method of claim 1.

Guschin et al disclose drying an array of micromatrices of polyacrylamide gel pads on a support for use in immobilizing a compound such oligonucleotide. See the abstract (page 203, left col); the paragraph bridging pages 202 and 204;; page 205, left col, first complete paragraph; page 207, right col under "Microchip Fabrication"; and page 211, left col, under "CONCLUSION".

Khrapko et al (col 4, lines 1-15) and Chetverin et al (col 12, lines 55-62) disclose providing an array of porous polymer gel pads containing an oligonucleotide on the surface of a solid support and then drying the array of porous polymer gel pads on the surface. Chetverin et al disclose the polymer gel being lyophilized or dried in vacuo (col 12, lines 58-59).

Funk et al disclose freeze drying swollen, non-porous, hydrophilic polymers to obtain porous, hydrophilic, highly swellable polymers having a desired pore size and pore distribution (col 2, line 58 to col 3, line 10), and which retain their original shape (col 3, lines 7-8). Monomers used to prepare the polymer can be amides of acids such as acrylic acid (col 3, lines 45-51). The amount of water in the swollen polymer being freeze dried can be used to control the pore size of the freeze dried polymer (col 3, lines 16-18).

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Ruchel (1978), Ruchel (1975) and Blank et al disclose freeze drying polyacrylamide gels to obtain porous polyacrylamide polymers.

It would have been obvious to carry out the drying of the array of polymer gel pads on the support of Guschin et al or Khrapko et al or Chetverin et al by freeze drying to obtain the function of freeze drying to produce a porous, highly swellable polymer of a controlled desired pore size and pore distribution as disclosed by Funk et al. It would have been expected that freeze drying can be used to increase the pore size since Funk et al disclose using the amount of water in the swollen polymer freeze dried to obtain a desired pore size. Adding an oligonucleotide probe to the pads would have been obvious since Guschin et al, Khrapko et al and Chetverin et al add an oligonucleotide to the pads. Selecting a DNA or RNA probe would have been a matter of choice depending on the use intended. The further disclosure of Ruchel (1978), Ruchel (1975) or Blank et al of freeze drying a polymer gel to obtain a porous polymer, if needed, would have further suggested carrying out the drying of Guschin et al, Khrapko et al or Chetverin et al by freeze drying. Ruchel (1978), in particular, discloses that freeze drying produces a sponge like structure without gel matrix shrinkage (page 564, lines 15-18).

Response to Arguments

Applicant's arguments filed 6/4/03 have been fully considered but they are not persuasive.

It is granted as urged by applicants that Guschin et al, Khrapko et al and Chetverin et al do not disclose freeze drying to increase

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pore size. However, Guschin et al and Khrapko et al disclose drying porous polymer gels, and Chetverin et al discloses lyophilizing (col 12, lines 58-59) which is freezing drying. Since Funk et al disclose freeze drying a polymer gel to obtain a porous polymer gel having a
5 desired controlled pore size and distribution, and the polymer freeze-dried is of the type dried by Guschin et al, Khrapko et al or Chetverin et al, it would have been obvious to freeze-dry the polymer gel of Guschin et al, Khrapko et al or Chetverin et al to obtain the result of a controlled pore size and distribution as suggested by Funk
10 et al. The references are applied together, and be considered in combination as a whole.

Applicants urge that Blank et al and Ruchel (1975) and (1978) do not teach that freeze-drying will increase pore size. However, these references are combined with the Funk et al patent, which suggests that
15 freeze-drying can be used to increase pore size.

Applicants urge that there is no motivation to combine Funk et al with Guschin et al, Khrapko et al or Chetverin et al. However, there is clear motivation. The motivation is to obtain in Guschin et al, Khrapko et al or Chetverin et al the function of freeze-drying when
20 used to dry a polymer gel as disclosed by Funk et al, i.e. to obtain the result of producing a dried polymer gel having a controlled pore size and pore distribution (Funk et al, col 3, lines 15-30).

Obviously, controlling pore size and distribution when drying in Guschin et al, Khrapko et al or Chetverin et al would have been
25 expected to an advantage since each reference is drying a porous

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polymer gel. Furthermore, when freeze-drying the polymer gel of Guschin et al, Khrapko et al or Chetverin et al, a larger pore size will inherently be obtained as compared to using other methods of drying. In the present invention, the pore size increase is with
5 respect to drying methods other than freeze-drying since the improvement as disclosed in the specification is using freeze-drying in place of known drying methods.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**
10 **FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

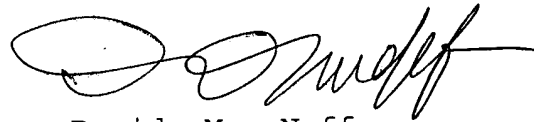
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date
15 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
20 however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be
25 reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

- 5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
10/3/03